

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Application of

JEFFERY W. KREAMER

Serial No. 08/071,052

Filed June 4, 1993

For: ASPIRIN AND VITAMIN
AND/OR TRACE ELEMENT
COMPOSITIONS FOR THE
PREVENTION AND TREATMENT
OF VASCULAR DISEASE

Group Art Unit 1205

Examiner: T. Criares

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.132

Dear Sir:

I, Larry H. Hollier, M.D., declare as follows:

1. I received my bachelor of science degree in 1964 from Louisiana State University, and my medical degree in 1968 from Louisiana State University School of Medicine. My internship and residency were at Charity Hospital of Louisiana in New Orleans, Louisiana.

2. I have received certification in general vascular surgery in 1983 and 1991, and have been certified by the American Board of Surgery in 1976 and 1987.

3. I have been a fellow of the American College of Surgeons since 1977 and a fellow in the American College of Cardiology since 1981.

4. I have been a member of the International Society for Cardiovascular Surgery since 1989, and a member of the American Surgical Association since 1990.

5. I have been a member of the American College of Physician Inventors since 1992, and a member of the American Heart Association, Council on Cardiothoracic and Vascular Surgery since 1992.

6. I have published, either alone or in conjunction with others, over 200 articles addressing topics relating to vascular medicine.

7. From 1976 until 1979 I was an Assistant Professor then Associate Professor of Surgery at the Louisiana State University Medical School.

8. From 1980 until 1987 I was an Assistant Professor then Associate Professor of Surgery at the Mayo Medical School.

9. From 1987-1993 I was chairman of the Department of Surgery at the Ochsner Clinic in New Orleans, Louisiana, and on the staff executive committee of the Alton Ochsner Medical Foundation in New Orleans, Louisiana.

Currently, I am chairman of the Department of Surgery and Executive Director of Clinical Affairs at Health Care International (Scotland).

10. I am familiar with the subject matter of the above-identified Patent Application.

11. Multi-vitamins are the most typical type of over-the-counter vitamin supplement taken by the general public.

12. Most leading multi-vitamin tablets typically contain the following vitamins: Vitamin A, Vitamin B-6, Vitamin C, Vitamin E and Niacin (typically d liver d as Niacinamide).

13. Most multi-vitamin tablets contain one or more of the following trace elements: selenium, zinc, iron, copper, cobalt and manganese.

14. The results of the unpublished observational study conducted by the University of Southern California, noted in the above-identified Application, shows unexpectedly beneficial results from the combination of aspirin and vitamins taken by the test subjects.

15. The attached graphic representation of the data collected in the University of Southern California study shows that the anticipated additive effect of weekly administrations of aspirin with vitamins would be a slight increase in deaths, the known benefits of aspirin and vitamins notwithstanding.

16. The results of the University of Southern California study show that the weekly administration of aspirin in combination with vitamins reduces the risk of cardiovascular deaths, myocardial infarction, ischemic heart disease, other heart disease, and total deaths more than either the weekly administration of aspirin alone or the administration of vitamins alone.

17. The University of Southern California data shows that the anticipated benefits of combining the weekly combination of aspirin with the administration of vitamins would be detrimental to the health of individuals so treated.

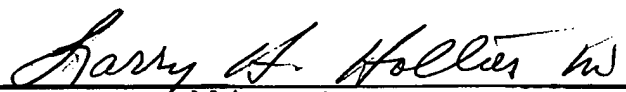
18. The results of the University of Southern California study show that the actual effect of weekly administration of aspirin in combination with vitamins is a reduction in the risk of cardiovascular deaths, myocardial infarction, ischemic heart disease, other heart disease, and total deaths beyond the additive effect of the weekly administration of aspirin in combination with vitamins anticipated by the data.

19. Contrary to the anticipated deleterious effects of combining weekly administrations of aspirin along with vitamins, the University of Southern California study shows the actual effect of weekly administration of aspirin with vitamins is unanticipatedly beneficial to individuals so treated.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

3/1/94


Larry H. Hollier, M.D.